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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/868,974 | 06/20/2001 | Mark Laurence Brader | X-11869 | 9992 |

7590 11/03/2004
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Lilly Corporation Center/DC 1104
Indianapolis, IN 46285

EXAMINER

ROBINSON, HOPE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1653

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,974

Applicant(s)

BRADER ET AL.

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30,33-37,40-44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30,33-36,40-44 and 47 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Office Action mailed February 12, 2004 on August 23, 2004, is acknowledged.
2. Claims 31-32, 38-39 and 45-46 have been canceled. Claims 27-30, 33-37, 40-44 and 47 are pending and are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The following grounds of objection/rejection are or remain applicable:

Claim Objection

5. Claims 28, 34-35, 37, and 42 are objected to because of the following informalities:
Claim 28, 35 and 42 are objected to because the claim recites "about 8.2 to about 8.5" with regard to the pH range and the independent claim recites a pH range of "about 8.2 to about 8.8", thus claims 28, 35 and 42 do not further limit claims 27, 34 and 41, as the about language recited could result in the same pH range in both claims. Note also that the specification does not provide a definition for "about" thus, about could mean plus or minus three points from the given range. It is suggested that the word "about" is deleted in both claims or claims 28, 35 and 42 are cancelled.

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Claim 34 is objected to because the claim has an extraneous period following the pH of "8.8".

Claim 37 is objected to as the claims depend from a rejected based claim.

Correction is required.

Claim Rejections - 35 U.S.C. § 112

6. Claims 27-30 and 33 remain rejected under 35 U.S.C. 112, first paragraph, enablement for the reasons of record.

Response to Applicant's Arguments:

The response on page 6 discusses rejections which have been withdrawn. Applicant's comments are noted, however, no further comments will be made as the rejections are no longer an issue. Applicant is basically arguing against a rejection under 35 U.S.C. 112, first paragraph because art has been applied to the instant claims. Note that a scope rejection has been made which indicates that the claims are not enabled for the full scope. The claimed invention is enabled for the disclosure in the art. However, the prior art cited does not enable the entire scope as claimed. The instant claims are directed to SEQ ID NO:2, known analogs and a further modification (comprises one additional amino acid). Adequate guidance is not provided as to where in the sequence the additional modification will occur and the effects of the interaction between the substituted residue and existing residues in the sequence. Further the claim recites the open language "comprises". The structure of the peptide cannot easily be envisioned by a skilled artisan. Predictability of which potential changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard

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to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (for example, expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function.

The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Further, a reference is provided which indicates that a single amino acid change can be detrimental to the protein's structure/function relationship (Tuddenham et al.). Thus, applicant's arguments are not persuasive and the rejection has been maintained.

7. Claims 27-30 and 33 remain rejected under 35 U.S.C. 112, second paragraph for the reasons of record.

Response to Applicant's Arguments:

The response on page 7 state that claim 27 is definite and the claim language of "additional amino acid substitution" means that it can occur anywhere in the GLP-1 molecule that is not contemplated by the variables X, Y, Z, R1 or R2. However, the claim does not say one

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additional amino acid except in the positions where the variables are, the fact that the claim language is ambiguous is the reason for the rejection of record. The claim recites "wherein said GLP-1 molecule further comprises" which is open language. It is suggested that claim 27 is amended to delete the word "comprises" in lines 3 and line 9. Regarding claim 28, applicant argues that the rejection is inconsistent with the law. Note that the rejection is now an objection, however, the claim remains rejected under this statute as it depends from claim 27.

Claim Rejections - 35 U.S.C. § 102/ § 103

8. Claims 27-29, 33-36, 40-43 and 47 remain rejected under 35 U.S.C. 102/103 for the reasons of record.

Response to Applicant's Arguments:

The response on page 7 states that the cited prior art includes a surfactant which is not found in the claimed invention, however, the claimed invention is a "shelf-stable solution formulation comprising...", and the open language "comprising" includes the prior art surfactant. The instant claims do not recite a negative proviso to exclude surfactant. Therefore, this argument is not persuasive and the rejection remains.

Conclusion

9. No claims are presently allowable.

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10. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

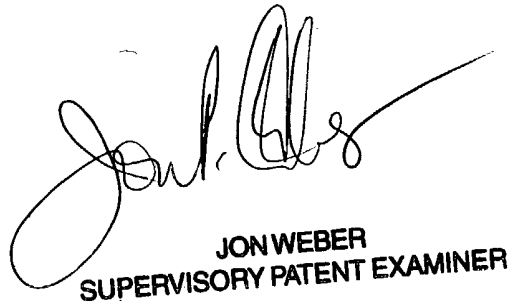
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

AR
10/25/04


JON WEBER
SUPERVISORY PATENT EXAMINER